OCT 20 2011 K101286

5 510(k) Summary

Summary as required by section 807.92(c)

Subscribers Name & Address

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Trade Names for SEDARA™ Gas Mixer System Components

SEDARA™ Gas Mixer	Article No PHX-0003
SEDARA™ Scavenger	Article No PHX-0038
SEDARA™ N_2O Cylinder	Article No PHX-0040

Device Classification

Common Name	*Classification*	*Class*	*Regulation Number*
Breathing Gas Mixer	BZR	II	21 CFR 868.5330
Apparatus, Gas-Scavenging	CBN	II	21 CFR 868.5430
Medical Gas Cylinder Package	ECX	Unclassified	21 CFR 868.6885

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
Nitronox First Response , Matrx	K883833
Passive Waste Scavenger , G Dundas Company	K080039

Intended Use & Indication for Use:

The SEDARA™ Gas Mixer System is indicated for mixing and delivering Nitrous Oxide (N_2O) and Oxygen (O_2), in a ratio of 1:1, at a fixed concentration of 50% / 50% (V/V), to spontaneously breathing patients of at least 15 kg body weight and four years of age, who have been examined by the attending physician prior to SEDARA™ System use and are under the continuous supervision of a healthcare professional in a clinical facility, such as a hospital, a free-standing ambulatory surgical center, or an outpatient clinic.

Device Description

USP N_2O and O_2 gases are blended to the 50%/50% concentration (V/V) and delivered upon demand to spontaneously breathing patients through a demand valve internal to the SEDARA™ Gas Mixer. Patient inspiration draws the gas mixture via a breathing circuit with a hand-held strapless face mask.

The Oxygen is supplied by the user either from a standard gas cylinder or from an O_2 wall outlet.

The Nitrous Oxide is supplied from a small cylinder equipped with a tamper-resistant valve.

The SEDARA™ Gas Mixer can be operated only with the use of a Security Key. The Security Key allows access and activation of the Gas Mixer, secures the N_2O Cylinder in use, and provides safekeeping of incremental N_2O Cylinders in the accompanying Transport Cart storage drawers, to guard against abuse and theft of the gas. The SEDARA™ Gas Mixer is provided with multiple levels of safety to ensure proper dosing. Visual and audible alarms signal the absence of adequate gas flow, the emptying of a gas cylinder, or technical failure of the mixer.

The gas exhaled by the patient into the face mask is channeled through the exhalation limb of the breathing circuit to the SEDARA™ Scavenger and removed via the hospital's waste gas disposal system.

Intended Patient Population:

The SEDARA™ Gas Mixer System is intended for delivery of the gas mixture to spontaneously breathing patients of at least 15 kg body weight and four years of age, who have been examined by the attending physician prior to SEDARA™ System use and are under the continuous supervision of a healthcare professional.

Substantial Equivalence:

SEDARA™ Gas Mixer is substantially equivalent to Nitronox K883833 gas mixer.

SEDARA™ Scavenger is substantially equivalent to the Passive Waste Scavenger K080039.

In comparison to the predicate device (Nitronox; K883833), the proposed gas mixer system has the same intended use and indications for use, uses a disposable face mask, is purely pneumatic and portable, connects to a small Nitrous Oxide Cylinder, mixes Nitrous Oxide and Oxygen to a 50%/50% (V/V) mixture with the same accuracy, and uses a demand valve for gas delivery. It includes a waste gas scavenger fully equivalent to the predicate scavenger (Passive Waste Scavenger; K080039).

The technical characteristics of the SEDARA™ Gas Mixer System do not introduce new questions regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 20 2011

Mr. Anders Palm
Director Medical Devices – Regulatory and Compliance
Linde Healthcare AB
Agavagen 54
Lidingo
Sweden SE 18181

Re: K101286
Trade/Device Name: SEDARA™ Gas Mixer System
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: II
Product Code: BZR
Dated: August 12, 2011
Received: August 15, 2011

Dear Mr. Palm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indication for Use Statement

510(k) Number K101286:

Device Name: SEDARA™ Gas Mixer System

Indication for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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